

Application No. 10/557,286
Paper Dated: December 3, 2008
In Reply to USPTO Correspondence of June 3, 2008
Attorney Docket No. 0470-053534

AMENDMENTS TO THE DRAWINGS

The attached three (3) Replacement Sheets of Drawings include changes to Figs. 1-3, respectively. Thus, the attached Replacement Sheets replace the original drawing sheets containing Figs. 1-3, respectively. The changes incorporated on the Replacement Sheets of Drawings are noted on the attached three (3) Annotated Sheets of Drawings.

Attachment: Replacement Sheets (3)
Annotated Sheets Showing Changes (3)

REMARKS

The Office Action dated June 3, 2008 has been reviewed and the Examiner's comments carefully considered. Claims 13-24 were pending in this application. Claims 13, 14, 16, 18, 19, 21, 23 and 24 have been amended and claim 25 has been added in accordance with the originally filed application. Thus, claims 13-25 are pending in the present application and claims 13 and 19 are in independent form.

Allowable Subject Matter

Initially, the Examiner is thanked for indicating that claim 19 contains allowable subject matter. In light of the amendments to the drawings and the amendments to claim 19 that incorporate the limitations of its base claim and intervening claim, it is respectfully submitted that independent claim 19 is in condition for allowance.

Objections to the Drawings

The drawings are objected to under 37 C.F.R. §1.83(a) because the five break locations, as claimed in claim 19, and the distance between these break locations, are not shown in the drawings. Figs. 1-3 have been amended herewith via the attached Replacement Sheets, with changes reflected on the attached Annotated Sheets, to illustrate the five break locations and their relative locations. Support for the amendments to Figs. 1-3 can be found at page 3, lines 18-19 of the originally filed specification. As such, entry of the Replacement Sheets and the amendments to Figs. 1-3, along with reconsideration and removal of these objections, are respectfully requested.

35 U.S.C. §112, First Paragraph, Rejections

Claims 14, 18, 21, 23 and 24 stand rejected under 35 U.S.C. §112, first paragraph, for allegedly failing to comply with the written description requirement. As to claim 14, the phrase "and is relatively soft at temperatures between 35°C and 40°C and in contact with moisture" has been deleted herewith. Regarding claim 18, the Examiner asserts that the phrase "at least two break points" is not supported by the specification or the drawings. Figs. 1-3 have been amended herewith to reflect five break points in the sleeve. Further, as discussed above, support for at least five break locations can be found at page 3, lines 18-19 of the originally filed specification. As such, Applicant respectfully asserts that proper support is found for a recitation of "at least two break points" in the present application. Thus, Applicant respectfully declines to delete this phrase from claim 18. However, in claim 18, the phrase "being 10 mm" has been replaced with "being 15 mm". As

Application No. 10/557,286
Paper Dated: December 3, 2008
In Reply to USPTO Correspondence of June 3, 2008
Attorney Docket No. 0470-053534

to claim 21, "3 – 10 mm" has been replaced with "3 – 7 mm." Regarding claim 23, "0.1 – 1.5 mm" has been replaced with "0.5 – 1.5 mm". As to claim 24, the phrase "rings are" have been replaced with the phrase "sleeve is".

In light of the foregoing, reconsideration and removal of these rejections are respectfully requested.

Art Rejections

Claims 13, 14 and 17 stand rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent Application Publication No. 2003/0097079 to Garcia (hereinafter, "Garcia").

Independent claim 13, as amended herewith, is directed to an insertion sleeve assembly comprising an insertion instrument for performing a medical operation and a sleeve of bio-absorbable material defining an interior for guiding said instrument. The sleeve has an opening and comprises a stop adjacent the opening. Further, the sleeve is made of a material that is relatively rigid outside the body and becomes softer after introduction into the body and collapses onto itself when the instrument is withdrawn.

Garcia does not teach or disclose the presently claimed invention and, as such, one of ordinary skill in the art would not look to the teachings of Garcia in order to arrive at the subject matter of the presently claimed invention. Garcia discloses a needle introduction sheath for use when removing a biopsy sample via a needle from an organ, such as a lung, liver, etc. from a body. However, there is no discussion in Garcia regarding what occurs when such biopsy sample actually exits the body and could be exposed to the skin of the body, causing potential contamination to the skin. With Garcia, there is only a rigid tube provided to give protection to the biopsy sample itself. In contrast to Garcia, and as is provided with the presently claimed invention, after introduction of the sleeve and insertion instrument into a body, the sleeve of the present invention extends from the target organ, through intervening tissues and organs, and subsequently, out through the skin of the body. As such, during withdrawal of the insertion instrument, contamination with cells retrieved from the target organ does not occur to the intervening tissues and organs, including the skin of the body. The presence of the stop adjacent the opening of the sleeve of the invention of amended claim 13 abuts against the skin surface of the body, preventing such potential skin contamination. As such, and in light of the amendments to independent claim 13, Applicant

Application No. 10/557,286
Paper Dated: December 3, 2008
In Reply to USPTO Correspondence of June 3, 2008
Attorney Docket No. 0470-053534

respectfully requests reconsideration and withdrawal of the anticipation rejection of independent claim 13.

Dependent claims 14 and 17 depend directly from, and add further limitations to, independent claim 13, and are believed patentable for the reasons stated herein.

Claims 15 and 16 are rejected under 35 U.S.C. §103(a) as being obvious over Garcia in view of United States Patent No. 6,884,427 to Barrows (hereinafter, "Barrows").

As discussed above, Garcia does not provide for protection of the skin of the body once the insertion instrument is taken out from the body, as is provided in presently amended claim 13. Barrows fails to teach or disclose a physical mechanism for such protection as well. Accordingly, Barrows fails to rectify the skin protection deficiency of Garcia. As such, even if the teachings of Garcia and Barrows were combined, the resulting combination would not disclose all of the claim elements of amended claim 13. Thus, Applicant respectfully submits that independent claim 13, as amended, is patentable and non-obvious over the combination of Garcia and Barrows.

Rejected claims 15 and 16 depend directly from independent claim 13, and are further believed patentable for the reasons stated herein. As such, reconsideration and withdrawal of the rejections under 35 U.S.C. §103(a) in view of Garcia and Barrows are respectfully requested.

Claims 18, 20, 22 and 23 are rejected under 35 U.S.C. §103(a) as being obvious over Garcia in view of United States Patent No. 4,838,280 to Haaga (hereinafter, "Haaga").

As discussed above, Garcia does not provide for protection of the skin of the body once the insertion instrument is taken out from the body, as is provided in presently amended claim 13. Haaga fails to teach or disclose a physical mechanism for such protection as well. Instead, Haaga is directed to a sheath that is used to minimize bleeding at the biopsy site. Accordingly, Haaga fails to rectify the skin protection deficiency of Garcia. As such, even if the teachings of Garcia and Haaga were combined, the resulting combination would not disclose all of the claim elements of amended claim 13. Thus, Applicant respectfully submits that independent claim 13, as amended, is patentable and non-obvious over the combination of Garcia and Barrows.

Rejected claims 18, 20, 22 and 23 depend directly or indirectly from independent claim 13, and are further believed patentable for the reasons stated herein. As

Application No. 10/557,286
Paper Dated: December 3, 2008
In Reply to USPTO Correspondence of June 3, 2008
Attorney Docket No. 0470-053534

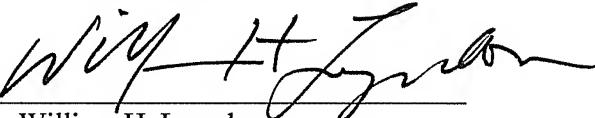
such, reconsideration and withdrawal of the rejections under 35 U.S.C. §103(a) in view of Garcia and Haaga are respectfully requested.

CONCLUSION

Based on the foregoing amendments and remarks, reconsideration of the rejections and allowance of claims 13-25 are respectfully requested.

Respectfully submitted,

THE WEBB LAW FIRM

By 

William H. Logsdon
Registration No. 22,132
Attorney for Applicant
436 Seventh Avenue
700 Koppers Building
Pittsburgh, PA 15219
Telephone: (412) 471-8815
Facsimile: (412) 471-4094
E-mail: webblaw@webblaw.com